

**Notice of Allowability**

Application No.

10/532,104

Examiner

Celia Chang

Applicant(s)

MATSUNAGA ET AL.

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1625

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 05/31/06 preliminary amendment and examiner's amendment attached.
2. ☒ The allowed claim(s) is/are 1,13-23,51,54,55 and 79.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

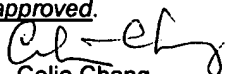
\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other drawings are approved.

  
Celia Chang  
Primary Examiner  
Art Unit 1625

### **DETAILED ACTION**

1. Petition filed under 37 CFR 1.102D has been decided and the decision was mailed April 28, 2006. Claims 2-12, 24-50, 56-67, 72-73 have been canceled. Claims 1, 13-23, 51-55, 68-71 and newly added 74-79 were presented.

#### *Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 13-23, 51-55, 74-79, drawn to crystalline compound, classified in class 546, subclass 153.
- II. Claims 68-71, drawn to method of treating tumors, diabetic retinopathy etc, classified in class 514, subclass various, depending on species election. If this group is elected, a further election of a single disclosed pathology is also required.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of treating tumor can be practice with well known antitumor agents such as taxol.

During a telephone conversation with J. Derek Mason on May 23, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 13-23, 51-66, 74-79. Affirmation of this election was made by applicant with a preliminary amendment dated May 31. Claims 2-12, 24-50, 56-73 have been canceled without prejudice against applicants' filing of divisional applications of the non-elected subject matter.

Claims 1, 13-23, 51-55, 74-79 are pending.

**2. Examiner's amendment**

Authorization for this examiner's amendment was given in a telephone interview with J. Derek Mason on Jun. 29, 2006.

Claim 51. (currently amended)

A process for producing crystalline N-{2-chloro-4-[(6,7-dimethoxy-4-quinolyl)oxy]phenyl}-N'-(5-methyl-3-isoxazolyl)urea monhydrochloric acid salt monohydrate, said process comprising the steps of:

adding hydrochloric acid to a solution of N-{2-chloro-4-[(6,7-dimethoxy-4-quinolyl)oxy]phenyl}-N'-(5-methyl-3-isoxazolyl)urea in an aprotic polar solvent selected from N,N-dimethylformamide and N,N-dimethylacetamide;

adding ethanol and water to the above solution to precipitate crystals from the solution.

Claims 52 and 53, 74-78 are canceled.

**3. Reason for Allowance**

The following is an examiner's statement of reasons for allowance:

Applicants have limited the claims to one compound which was disclosed on pages 7-8 of the specification. This compound has been properly provided with its nomenclature by CAS (see CA140:363009, RN 682745-41-1) and the name has been properly incorporated as claim 1. Such product has an advantage over the known compound in that it was found that hygroscopicity for the claimed compound to be on a low level, thus, is expected to have the advantage to be stable under high humidity conditions (see p.76 and p. 2 of the specification). The closest prior art was found in US 6,821,987 wherein a hydrochloric acid salt was prepared. The reference disclose generically possible formation of solvate. However, no solvate in any form or with any solvent or water was described and the formation of the hydrochloric acid addition salt of the instantly claimed compound was crystallized from non-aqueous solutions, thus, free

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from any hydrate (see col. 22, example 21, lines 53-63). Claims 1, 13-23, 51, 54-55, 79 are allowed.

The references cited on PTO-892 which are not applied are considered relevant to the state of the art.


Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jun. 29, 2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625